list

ATTACHMENT E

Selection of Soil Ingestion Rates

In assessing exposures and risks from the ingestion of floodplain soil, the HHRA evaluates eleven exposure scenarios (including residential, recreational, agricultural, and commercial/industrial scenarios). Within each scenario, different age categories of potentially exposed human populations are assessed. Depending upon the scenario, the age groups considered include young children (aged 1 to 6 years), older children (aged 7 to 18 years), and/or adults.

The ingestion rates used for the different exposure scenarios and age groups in the HHRA are summarized in Table 1. Generally speaking, when characterizing RME exposures to floodplain soils, the HHRA uses upper-bound soil ingestion rates of 200 mg/day for young children (1 to 6 years of age) and 100 mg/day for older children and adults. For the CTE exposures, the HHRA generally uses soil ingestion rates of 100 mg/day for young children and 50 mg/day for older children and adults. Exceptions to these rates include:

- the ATV/dirt biking scenario, for which 200 and 100 mg/day are used to evaluate exposures to older children under the RME and CTE scenarios, respectively;
- the marathon canoeist scenario, for which 50 mg/day is used for both the RME and CTE ingestion rates for adults;
- the agricultural scenario, which uses enhanced adult soil ingestion rates of 200 mg/day and 100 mg/day for the RME and CTE analyses, respectively; and
- the utility worker scenario, for which enhanced adult soil ingestion rates of 330 mg/day and 100 mg/day are used to evaluate the RME and CTE exposures.

As described in the HHRA (Vol. IIIA, p. 4-28), the general soil ingestion rates were based on studies conducted prior to 1997 and discussed in EPA's *Exposure Factors Handbook* (EFH) (EPA, 1997). However, improved, more recent studies of soil ingestion by both children and adults, which have been published in the peer-reviewed literature, indicate that these daily rates are overestimated. Because of improvements in study methodologies, the results of these more recent studies are more representative of potential exposures to these individuals. Specifically, two recent studies (discussed below), published by the authors of the studies upon which EPA has based its upper-bound estimates, provide the most objective information for use in deriving

high-end estimates of daily soil intake. Adoption of these more recent data would be consistent with EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (EPA, 2002), which identify information suitable for inclusion in risk assessments as "the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies."

In addition, the HHRA uses two different estimates of "enhanced" soil ingestion rates to evaluate potential exposures to farmers and utility workers. A review of the available data on adult ingestion rates, as well as recent information on the adherence of soil to the hands of farmers and utility workers, indicates that these enhanced soil ingestion rates should likewise be reduced.

Finally, the HHRA assumes that all soil ingested during a day of exposure for the recreational scenarios is derived exclusively from the EA being evaluated. This assumption overestimates exposures via these scenarios because recreational activities generally only occupy a small portion of a day of exposure. The total volume of soil ingested in a day will be derived from a combination of the floodplain areas and areas wholly unrelated to the floodplain that are contacted during each day of exposure.

Soil Ingestion Rates for Younger Children

The HHRA uses a soil ingestion rate of 200 mg/day to evaluate RME exposures to 1 to 6 year old children. EPA originally recommended this rate in its *Risk Assessment Guidance for Superfund* (EPA, 1991) and reiterated that recommendation in its EFH (EPA, 1997) as a "conservative estimate of the mean." The latter recommendation was based primarily on tracer studies in children (ages 1 through 5) that were undertaken by Calabrese and his coworkers (Calabrese et al. 1989; Stanek and Calabrese, 1995a; 1995b). However, updated studies by these same authors, conducted using improved methodologies and published since that guidance was released, indicate that these previous estimates are overestimates and can be refined and improved.

The most recent such study in children was published by Stanek et al. (1999) and Stanek and Calabrese (2000). As described by Stanek and Calabrese (2000), this study implemented

several improvements in study design and analytical procedures that occurred since the publication of their earlier papers and that led to an improved estimate of the 95th percentile soil ingestion estimate for this age group. The advantages of this recent study included: (1) a relatively large study group (n = 64 children); (2) improved particle size measurements that focused attention on soil of smaller particle size; (3) a longer study duration (365 days); (4) randomized selection of participants; (5) the use of a relevant age group (1 to 4 year old children); (6) use of a random sample of the population for that age group; and (7) better control for input/output error. The soil ingestion rates reported by Stanek and Calabrese (2000) for these children were:

- A 95th percentile rate of 106 mg/day (when evaluated over a 365-day period);
- An arithmetic mean ingestion rate of 31 mg/day; and
- A median (50th percentile) ingestion rate of 17 mg/day.

This study also calculated the best linear unbiased predictors of the 95th percentile of soil ingestion over different time periods and reported the following results:

- Over a 7-day exposure period, the 95th percentile soil ingestion rate was 133 mg/day;
- Over a 30-day exposure period, the 95th percentile soil ingestion rate was 112 mg/day;
- Over a 90-day exposure period, the 95th percentile soil ingestion rate was 108 mg/day; and
- Over a 365-day exposure period, the 95th percentile soil ingestion rate was 106 mg/day.

These data suggest that, as the length of time that the children are studied increases and as the precision of the analysis improves (i.e., reduced uncertainty), the daily ingestion rates decline. This is reasonable due to the fact that daily fluctuations in soil ingestion rates will tend to average out over time. This narrowing of the distribution in the soil ingestion estimates when daily variability and uncertainty are reduced is not unexpected and is referred to as “regression to the mean” (Stanek and Calabrese, 2000). As noted by Stanek and Calabrese (2000), these longer-term estimates are more appropriate when assessing risks and hazards associated with chronic exposure, as is the case in the HHRA.

In a presentation to EPA Region 1 in May 2002, Dr. Calabrese explained these points and recommended, based on this more recent study, that the soil ingestion rates to be used for

young children in recreational scenarios should be 100 mg/day for the upper bound and 20 mg/day (based on the median in this study) for the central tendency estimate. Dr. Calabrese has reiterated these recommendations in a recent letter to GE, a copy of which is attached as Exhibit E.1. GE agrees with these recommendations and urges that the HHRA be revised to use these rates as the general soil ingestion rates for 1 to 6 year old children in residential and recreational exposure scenarios.

Soil Ingestion Rates for the Older Child and Adult

As noted in the HHRA (Vol. IIIA, p. 4-28), the general soil ingestion rates used to evaluate exposures to older children and adults (100 mg/day for the RME and 50 mg/day for the CTE) were based primarily on a 1990 study conducted by Calabrese et al. (1990). Again, however, there is now a more recent study of adults by the same investigators (Stanek et al., 1997), which included a number of improvements over the 1990 study: (1) a larger number of subjects and days of participation; (2) improved study design that considered seven consecutive days of fecal sampling; (3) improved selection of soil tracers; (4) a broader range of soil ingestion validation; and (5) enhanced capacity for additional assessments including particle size of the soil ingested. The result was more reliable daily estimates of soil ingestion and a greater capacity for more reliable long-term modeling estimates.

The 1997 study was not without complications, however. Of the ten adults participating in the study, one had an unusually high soil ingestion estimate (2 grams) for the first day of the study week. This high estimate resulted in an inflated upper percentile estimate of the overall ingestion rates. In fact, Stanek et al. (1997) stated that "the 95th percentile soil ingestion estimate was 331 mg/day, but based on present data, it is substantially uncertain" because of the results from this one subject. Further, as described by Dr. Calabrese (a co-author of the paper) in his attached letter, this subject had four times higher freeze-dried fecal weight on the first day than on any other day of the study, thus suggesting that his excretion on that day reflected a multi-day accumulation, instead of just one day, as assumed in the calculations. This fact confirms that the 95th percentile value from this study, which is driven by the result for this one subject, is not only uncertain but substantially overestimated. Due to this aberrant result from one participant, Dr. Calabrese has recommended, in his attached letter, that the upper 75th percentile (49 mg/day, rounded to 50 mg/day) from the Stanek et al. (1997) study is the most appropriate value to use as an estimate of high-end soil ingestion by adults. He has

also recommended use of a value of 10 mg/day for the central tendency estimate. This is consistent with the results of Stanek et al. (1997), who reported an adult mean daily soil ingestion estimate of 6 mg/day, and it represents 50 percent of the young children's median rate Again, GE supports these recommendations.

Enhanced Soil Ingestion Rates

EPA has used an "enhanced" soil ingestion rate of 330 mg/day to evaluate RME exposures to utility workers. This estimate represents the 95th percentile value for adults reported by Stanek et al. (1997). As stated previously, the authors of that study noted that this estimate was "substantially uncertain," and its use is not recommended by one of the study's co-authors, Dr. Calabrese, as noted in his attached letter.

EPA has used a different enhanced soil ingestion rate of 200 mg/day to estimate RME soil ingestion exposures to farmers. As explained in the HHRA (Vol. IIIA, pp. 4-28 – 4-29), this was the 90th percentile value reported by Stanek et al. (1997). Thus, it also has a high level of uncertainty associated with it.

GE recognizes that soil ingestion by utility workers and farmers may be greater than ingestion by typical adults due to the increased potential for more soil to adhere to their hands during these activities. According to EPA's (2001) dermal guidance, the 95th percentile soil adherence rate for the hands of utility workers is 0.821 mg/cm^2 and the 95th percentile adherence rate for the hands of farmers is 0.826 mg/cm^2. If these empirically based adherence factors are combined with the assumption that workers would ingest the amount of soil that could coat the inside surface of the fingers and thumbs (14 percent of the total surface area of the hands, based on the Hawley (1985) approach), the result is an enhanced daily soil ingestion rate of approximately 105 mg/day for both populations.

The Massachusetts Department of Environmental Protection (MDEP) has evaluated the available soil ingestion data for adults and concluded that 100 mg/day is a reasonable estimate of enhanced ingestion (MDEP, 2002). In addition, in developing PCB cleanup standards for areas outside the River under the Consent Decree executed by GE, EPA, and other parties covering the present site, EPA used an enhanced soil ingestion rate of 137 mg/day to develop its cleanup standard based on utility workers' exposure (EPA, 1999). That value was based on

a prior recommendation by GE (1997) for an enhanced soil ingestion rate, which was also based on the Hawley (1985) approach but used a more conservative dermal adherence factor of 1 mg/cm^2. GE believes that this estimate would be a reasonable upper-bound enhanced soil ingestion rate for both the utility worker and the farmer (since, as noted above, the soil adherence data do not show any significant difference between them). Thus, to be consistent with the approach that EPA used for areas outside the River, GE recommends that the HHRA be revised to incorporate the same enhanced soil ingestion rate of 137 mg/day for RME exposures in the utility worker and agricultural scenarios.

Fraction Contaminated

For the recreational scenarios included in the HHRA, it is expected that the recreators would spend only a portion of any given day of exposure engaged in recreational activity in or near the floodplain. In some cases (e.g., walking a dog), these exposures will be very brief. The remaining source for soil contact during the remainder of the day will include home-, work-, and school-based activities that occur outside the floodplain. For these scenarios, a further adjustment should be made to the daily soil ingestion rates to account for the portion of the recreators' daily soil intake that derives from areas wholly unconnected with the floodplain – i.e., the time they spend at home (indoors or outdoors), at work or school, or in other areas unrelated to the floodplain.

Such an approach is supported by EPA guidance (EPA, 1989, pp. 6-39, 6-40), which recommends inclusion of a factor (FI) to account for the fraction of soil that is ingested from the contaminated source. Indeed, in past recreational evaluations, EPA Region I has made such an adjustment to reflect the non-site-related portion of the receptors' daily soil ingestion. In developing its cleanup levels for areas outside the River under the Consent Decree, EPA (1999) utilized an FI of 0.5 for its recreational exposure scenario to reflect the fraction ingested from the site as opposed to other areas during a day of exposure. This is a reasonable assumption and should be used when evaluating direct contact exposures for recreational scenarios in the Rest of River floodplain.

Note that this adjustment is separate from the adjustment discussed in Section 3.2.2 and Attachment D of these comments. That adjustment was intended to reflect the fact that, where the actual overall exposure area includes portions both within and outside the 1 ppm isopleth, a

portion of the receptor's exposure within that overall exposure area in or near the floodplain will occur outside 1 ppm isopleth. The adjustment discussed in this attachment is intended to reflect the fact that, in most cases, a large portion of the receptors' daily soil intake will occur in areas that have nothing to do with the floodplain – i.e., home, school, work, etc.

Conclusions

For the reasons discussed above, GE urges that the HHRA be revised to: (1) adopt general soil ingestion rates based on the more recent and improved studies (Stanek and Calabrese, 2000, for young children; Stanek et al., 1997, for older children and adults); (2) use an enhanced soil ingestion rate of 137 mg/day to evaluate potential RME exposures to utility workers and farmers; and (3) incorporate an additional adjustment factor of 0.5 into the soil ingestion equations for the recreational scenarios to account for the limited contribution of floodplain soil to the total volume of soil ingested daily.

References:

Calabrese, E.J., R. Barnes, E.J. Stanek, H. Pastides, C.E. Gilbert, P. Veneman, X.R. Wang, A. Lasztity, and P.T. Kostecki. 1989. How much soil do young children ingest: an epidemiologic study. *Regul. Toxicol. Pharmacol.* 10:123-37.

Calabrese, E.J., E.J. Stanek, C.E. Gilbert, and R.M. Barnes. 1990. Preliminary adult soil ingestion estimates: results of a pilot study. *Regul. Toxicol. Pharmacol*. 12:88-95.

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Stanek, E.J., E.J. Calabrese, and R.M. Barnes. 1999. Soil ingestion estimates for children in Anaconda using trace element concentrations in different particle size fractions. *Human and Ecologic Risk Assessment* 5:547-558.

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Table 1. Summary of Soil Ingestion Rates Used in the HHRA

Scenario/Receptor	RME	CTE
Residential Cancer (age-adjusted for younger child through adult) *	135.7 mg-yr/kg-day	46.4 mg-yr/kg-day
Residential Noncancer (younger, older child and adult)	200 mg/day (younger child) 100 mg/day (adult)	100 mg/day (younger child) 50 mg/day (adult)
General Recreation (younger, older child and adult)	200 mg/day (young child) 100 mg/day (older child) 100 mg/day (adult)	100 mg/day (young child) 50 mg/day (older child) 50 mg/day (adult)
ATV/Dirt and Mountain Bike (older child)	200 mg/day	100 mg/day
Marathon Canoeist (adult)	50 mg/day	50 mg/day
Recreational Canoeist/Boater (older child and adult)	100 mg/day (older child) 100 mg/day (adult)	50 mg/day (older child) 50 mg/day (adult)
Angler (older child and adult)	100 mg/day (older child) 100 mg/day (adult)	50 mg/day (older child) 50 mg/day (adult)
Waterfowl Hunter (older child and adult)	100 mg/day (older child) 100 mg/day (adult)	50 mg/day (older child) 50 mg/day (adult)
Sediment (older child and adult)	100 mg/day (older child) 100 mg/day (adult)	50 mg/day (older child) 50 mg/day (adult)
Farmer (adult)	200 mg/day	100 mg/day
Groundskeeper (adult)	100 mg/day	50 mg/day
Utility worker (adult)	330 mg/day	100 mg/day

*Age-adjusted factors for the RME are calculated assuming a younger child (weighing 15 kg) consumes 200 mg/day of soil for 6 years, while an adult (weighing 70 kg) consumes 100 mg/day of soil for 39 years. The CTE values assume the child consumes 100 mg/kg for 6 years and the adult 50 mg/day for 9 years (body weights remain the same).

EXHIBIT E.1

LETTER FROM DR. EDWARD CALABRESE
RE: SOIL INGESTION RATES

July 23, 2003

Kevin W. Holtzclaw
Manager – PCB Issues
General Electric Company
3135 Easton Turnpike
Fairfield, CT 06431

Re: Soil Ingestion Rates

Dear Mr. Holtzclaw:

The General Electric Company (GE) has asked for my opinion on the soil ingestion rates used by the U.S. Environmental Protection Agency (EPA) for general residential and recreational exposures in its June 2003 draft of the Human Health Risk Assessment (HHRA) for the Housatonic River. For upper bound exposures, those rates are 200 mg/day for young children and 100 mg/day for older children and adults. The central tendency estimates are 100 mg/day for young children and 50 mg/day for older children and adults. These rates are based on prior studies by our group – Calabrese et al. (1989) and Stanek and Calabrese (1995a, b) for young children, and Calabrese et al. (1990) for adults.

As explained in a presentation that I made on this subject to EPA Region 1 in May 2002, I believe that these rates are overstated and can be significantly improved by reliance on newer soil ingestion studies from our group, which used improved methodologies. I have reviewed the discussion of this topic in the document entitled "Attachment E: Selection of Soil Ingestion Rates," which GE sent me and which I understand will be part of GE's comments on the HHRA. I entirely agree with that discussion. To summarize:

1. Soil Ingestion Rates for Young Children. Our most recent study of soil ingestion rates in young children (Stanek and Calabrese, 2000) included several improvements over our prior studies. These included: 1) a relatively large study group (64 children); 2) improved particle size measurements that focused attention on soil of smaller particle size; 3) a longer study duration (365 days); 4) the use of a relevant age group (1 to 4 year old children); 5) use of a random sample of the population for that age group; and 6) better control for input/output error. The results of this study showed a 95th percentile soil ingestion rate of 106 mg/day (when evaluated over a year), a median (50th percentile) ingestion rate of 17 mg/day, and an arithmetic average ingestion rate of 31 mg/day. Based on these results, I recommend that the most appropriate soil ingestion rates to use for chronic exposures to young children would be an upper bound rate of 100 mg/day (based on the year-long 95th percentile value from our study) and a central tendency estimate of 20 mg/day (based on the median value from our study).

2. Soil Ingestion Rates for Adults and Older Children. Our most recent study of soil ingestion rates in adults (Stanek et al., 1997) likewise included a number of improvements over our prior (1990) study. These included: 1) a larger number of subjects (10) and days (28) of participation; 2) an improved study design that considered seven consecutive days of fecal sampling; 3) improved selection of soil tracers; 4) a broader range of soil ingestion validation; and 5) an enhanced capacity for additional assessments including particle size of the soil ingested. In this study, one of the participating adults had an unusually high soil ingestion estimate (2 grams) on the first day of the study week. In fact, on that day, this subject had 4 times higher freeze-dried fecal weight than on any other day of the study, suggesting that his excretion on that day reflected a 3-4 day accumulation, instead of just one day, as assumed in the calculations. In consequence, the 95th percentile ingestion rate from this study (331 mg/day), which is driven by that result for one subject, is uncertain, unstable, and artificially inflated. In these circumstances, I recommend that EPA use the upper 75th percentile value from this study, which was 49 mg/day, as the basis for an upper bound soil ingestion rate of 50 mg/day for adults and older children. For the central tendency estimate, I recommend use of an ingestion rate of 10 mg/day. This is consistent with the

mean soil ingestion rate observed in our 1997 study (6 mg/day) and would represent half of the central tendency rate that I have recommended for young children.

I appreciate the opportunity to review these materials. Please do not hesitate to contact me if you have any further questions.

Sincerely,

Ed Calabrese

Edward J. Calabrese, Ph.D.
Professor of Toxicology
Director of the Northeast Regional
Environmental Public Health Center

EJC/ps

References for Letter

Calabrese, E.J., R. Barnes, E.J. Stanek, H. Pastides, C.E. Gilbert, P. Veneman, X.R. Wang, A. Lasztity, and P.T. Kostecki. 1989. How much soil do young children ingest: An epidemiologic study. *Regul. Toxicol. Pharmacol.* 10:123-37.

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